

**REMARKS**

Reconsideration of this application and withdrawal of the rejections set forth in the non-final Office Action mailed August 20, 2010, is requested in view of this amendment and the following remarks. Claims 1-15, 17-19, 21-27, and 36-37 were pending and at issue prior to this amendment. By this amendment, claims 1, 4, 5, 15, 36, and 37 have been amended, and claims 2-3 have been canceled. The claims as amended are fully supported by the original specification as filed.

I. Rejection of Claim 36 under 35 U.S.C. Section 112, first paragraph

Claim 36 stands rejected under 35 U.S.C. Section 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that the specification fails to support the limitation in claim 36 reciting a marker wire having a first and a second end offset from each other in a circumferential direction and along the length of the medical device in combination with the first and second directional indicators that connect in an image to form a symbol when viewed in the proper rotation. Applicant respectfully submits that Fig. 9 indeed shows a marker wire having a first and second end offset from each other circumferentially and along the length of the device, in combination with the first and second directional indicators. For example, a marker wire comprising a portion extending longitudinally (e.g. portion 24 as shown in Fig. 3A) AND a portion extending circumferentially (e.g. portion 26 as shown in Fig. 3A), results in a marker wire having a first end and a second end offset from each other longitudinally and circumferentially. The description of Fig. 1 describing the marker wire 20, which is also shown in Fig. 9 as marker wire 20, explicitly states:

a wire marker 20 may comprise a first portion 24 extending along a portion of the length of the medical device 10, and a second portion 26 extending about a radial arc or circumferential portion of the medical device 10. The marker 20 may further include a

third portion 28 extending along a portion of the length of the medical device 10, and a fourth portion 30 extending about a radial arc or circumferential portion of the medical device 10.

(Specification, page 8, lines 2-4)

Accordingly, it is clearly supported in the specification that the marker wire 20 may include only the 2 segments comprising one longitudinal segment and one circumferential segment.

Moreover, there is no reason that this precludes also having the first and second directional indicators. The first and second directional indicators 36a and 36b are not required to be a part of the marker wire 20, and regardless, could be a part of the circumferential portion of the marker wire as shown in Fig. 9. the Any three of the segments making up the closed shape comprise a marker wire having a first and second end offset from each other circumferentially and along the length of the device. Clearly, this is in combination with the first and second directional indicators.

Thus, claim 36 is supported in the specification as filed, and this rejection should be withdrawn.

## II. Rejections under 35 U.S.C. Section 103(a)

Claims 1, 15 and 17 stand rejected under 35 U.S.C. Section 103(a) as being obvious over Makower '875 (U.S. Patent No. 6,302,875) in view of Ryan (U.S. Patent No. 6,576,009).

Claims 36 stand rejected under 35 U.S.C. Section 103(a) as being obvious over Makower '875 in view of Makower '311 (U.S. Patent No. 6,579,311 and Ryan.

Claims 1-7, 12, 15, 18, 19, 23-25 and 37 stand rejected under 35 U.S.C. Section 103(a) as being obvious over Makower '875.

Claim 17 stands rejected under 35 U.S.C. Section 103(a) as being obvious over

Makower '875 in view of Nash (U.S. Publication No. 2002/0032432).

Claim 21 stands rejected under 35 U.S.C. Section 103(a) as being obvious over Makower '875 in view of Makower '311 (U.S. Patent No. 6,579,311).

Claim 36 stands rejected under 35 U.S.C. Section 103(a) as being obvious over Makower '875 in view of Makower '311.

Claims 1-6, 13, 24, 25 and 37 stands rejected under 35 U.S.C. Section 103(a) as being obvious over Makower '311 in view of Makower '875.

Claim 27 stands rejected under 35 U.S.C. Section 103(a) as being obvious over Makower '311 in view of Makower '875 and further in view of Plaia (U.S. Patent No. 6,497,711).

Claims 1-6 and 24-26 stand rejected under 35 U.S.C. Section 103(a) as being obvious over Flaherty (U.S. Patent No. 6,660,024) in view of Makower '875.

Claims 1-5, 8-11 and 14 stand rejected under 35 U.S.C. Section 103(a) as being obvious over Lombardi (U.S. Patent No. 5,824,042) in view of Makower '875.

Claims 15, 19 and 22 stand rejected under 35 U.S.C. Section 103(a) as being obvious over Armstrong (U.S. Publication No. 2002/0099431) in view of Makower '875.

Applicant respectfully submits that the obviousness rejections should be withdrawn because none of the cited prior art discloses, suggests or otherwise render obvious the claimed apparatus comprising a medical device comprising, *inter alia*, a marker wire coupled to the medical device, the medical device having a length and a longitudinal axis, the marker wire comprising four contiguous portions defining the perimeter of a closed area, wherein two portions extend in a circumferential direction about the longitudinal axis of the medical device but not entirely about the circumference of the medical device, and two portions linearly extend in a direction parallel to the longitudinal axis of the medical device the closed area having a

length that is less than the length of the medical device, wherein the rotational orientation of the marker wire may be determined using an imaging device when the medical device is positioned within a bodily lumen; a first directional indicator coupled to said medical device and intersecting said marker wire, the first directional indicator comprising a first portion of a symbol said marker wire; a second directional indicator coupled to said medical device and intersecting said marker wire, said second directional indicator offset from said first directional indicator, the second directional indicator comprising a second portion of the symbol; wherein images of said first and second directional indicators physically connect to form the symbol when viewed from a proper rotational orientation about the longitudinal axis when viewed orthogonally to the longitudinal axis using an imaging device.

While the Supreme Court in *KSR International Co. v. Teleflex Inc.* ("KSR")<sup>1</sup> held that there are no rigid rules for determining obviousness, the Court reaffirmed that "rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinnings to support the legal conclusion of obviousness."<sup>2</sup> As reiterated by the Supreme Court in KSR, the framework for the objective analysis for determining obviousness under 35 U.S.C. §103 is stated in *Graham v. John Deere Co.*<sup>3</sup> Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

- (1) Determining the scope and content of the prior art;
- (2) Ascertaining the differences between the claimed invention and the prior art; and
- (3) Resolving the level of ordinary skill in the pertinent art; and

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<sup>1</sup> 550 U.S. \_\_\_, \_\_\_ (2007)

<sup>2</sup> 550 U.S. \_\_\_, \_\_\_ (2007)

<sup>3</sup> 550 U.S. \_\_\_, \_\_\_ (2007)

(4) Considering objective evidence (secondary considerations) indicating obviousness or non-obviousness.

Although the Court in KSR rejected rigid preventative rules in making an obviousness inquiry, the Court reaffirmed that there must be some articulated rationale in order to modify or combine the teachings of multiple references in making an obviousness rejection.<sup>4</sup> Furthermore, the combined teachings of the prior art must at least result in the Applicant's claimed invention.

Therefore, to establish a *prima facie* case of obviousness, the Examiner must establish three basic criteria: first, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; second, there must be a reasonable expectation of success; and finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Moreover, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). It is improper to pick and choose among features and elements found in the prior art references in a hindsight reconstruction of Applicants' claimed invention. *See e.g., In re Jones*, 958 F.2d 347, 350-51 (Fed. Cir. 1992); *In re Fritch*, 919 F.2d 720 (Fed Cir. 1990) ("It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious"). Furthermore, it is improper to combine the teachings of references where the references teach away from the asserted combination. MPEP § 2145. Applicant submits that the Examiner's obviousness rejection cannot be sustained consistent with these well-established requirements for obviousness.

First of all, none of the cited prior art discloses, teaches or suggest a marker wire comprising four contiguous portions defining the perimeter of a closed area, wherein two portions extend in a circumferential direction about the longitudinal axis of the medical device but not entirely about the circumference of the medical device, and two portions linearly extend in a direction parallel to the longitudinal axis of the medical device the closed area having a length that is less than the length of the medical device, wherein the rotational orientation of the marker wire may be determined using an imaging device when the medical device is positioned within a bodily lumen. For example, Makower '875 does not disclose a marker wire that has two portions extending linearly along the longitudinal axis of the medical device. The marker wire of Makower '875 is circular, and therefore has no linearly extending portions. Similarly, Makower '311 does not disclose a marker wire having the claimed configuration.

The marker of Flaherty has two linear portions, but it does not have two circumferential portions that do NOT extend entirely about the circumference. Thus, the circumferential portion are incapable of indicating the rotational orientation because they look the same at all rotational orientations, in marked contrast to Applicants' claimed invention.

Accordingly, none of the prior art teaches or suggests a marker wire according to Applicants' claimed invention.

Furthermore, none of the prior art teaches or suggests Applicants' claimed first and second directional indicators which each intersect the marker wire. The first and second directional indicators of Makower '875 are physically separated from the marker wire and they do not intersect. There is no teaching or suggestion in any of the cited prior art to modify Makower '875 to produce Applicants' claimed invention requiring the first and second

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<sup>4</sup> 550 U.S. \_\_, \_\_ (2007)

directional indicators to intersect the marker wire. The intersecting indicators of Applicants' invention provide additional accuracy and fidelity to the multiple markers.

Therefore, claims 1, 4-15, 17-19, 21-27, and 36-37 are not obvious over the cited prior art, and this rejection should be withdrawn.

Conclusion

Any claim amendments which are not specifically discussed in the above remarks are not made for reasons of patentability, do not affect the scope of the claims, and it is respectfully submitted that the claims satisfy the statutory requirements for patentability without the entry of such amendments. These amendments have only been made to increase claim readability, to improve grammar, or to reduce the time and effort required of those in the art to clearly understand the scope of the claim language.

In view of the foregoing remarks, Applicant respectfully submits that all of the Examiner's rejections have been overcome. Accordingly, allowance is earnestly solicited. If the Examiner feels that a telephone interview could expedite resolution of any remaining issues, the Examiner is encouraged to contact Applicant's undersigned representative at the phone number listed below.

Respectfully submitted,

Dated: November 18, 2010      By: \_\_\_\_\_ /James K. Sakaguchi/  
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